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No. 10-1031

In the Supreme Court of the United States

NATIONAL CORN GROWERS ASSOCIATION, ET AL.,
Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY, ET AL.,
Respondents.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

REPLY BRIEF FOR PETITIONERS

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INTRODUCTION

Because EPA tries to recast the decision below, we begin by restating the holding of the court of appeals on when a hearing is required under the statute and regulations at issue: "[T]he FFDCA and the EPA's regulations establish a 'summary-judgment type' standard for determining whether to hold a hearing: The EPA must hold a hearing if it determines an objection raises a material issue of fact." Pet. App. 6a. Critically, however, the court of appeals also held that a "dispute between experts"—which, as the court correctly stated, "accurate[ly]" describes the dispute in *this* case—is "fatal" to finding a disputed issue of material fact. *Id.* at 13a. And the court further held that judicial review of EPA's determination that an issue of disputed material issue does not exist is essentially hands off. *Id.* at 7a. That ruling not only directly conflicts with the decisions of this Court and other circuits, *see* Pet. 14-26, it effectively guts the statutory hearing right at issue in this case.

This case is a poster child for why the FFDCA's hearing requirement is necessary. It is undisputed both that (1) the pesticide that EPA essentially banned in the proceedings below—carbofuran—was used safely for four decades without a *single* incident of dietary or drinking water exposure causing any observable symptoms—let alone serious injury, and (2) that perfect safety record was accomplished even while the amount of carbofuran used was *50 times* greater than today, on as many as 35 domestic crops grown widely throughout the country. *See* Pet. 7-8; *cf. Winter v. NRDC*, 129 S. Ct. 365 (2008) (emphasizing absence of any documented case of harm to marine mammals despite 40-year history of naval exercises at issue).

Yet at significant economic and practical expense to American businesses, farmers, and consumers, EPA has now banned the use of that product without even affording the manufacturer a hearing on safety—based on the premise that it is so obvious that carbofuran is *unsafe* at the much, much *lower* levels that are used today that there is not even a disputed issue of material fact warranting a hearing.

As a common sense matter, that conclusion does not pass the straight face test. And as a legal matter, the conclusion cannot be squared with the standard that EPA itself "agree[d]" governs this case (Pet. App. 6a)—and that follows from the decisions of this Court and those of other circuits. Pet. 20-25. Moreover, EPA's implausible conclusion that no material issue of fact exists not only fails to account for the mountain of expert evidence petitioners presented showing that carbofuran is safe at the levels at issue, *see* Add. 1a-8a, but is based on completely unrealistic assumptions. For example, EPA assumed that *100%* of every relevant crop—everywhere—would be treated by carbofuran simply because that was "legally permissible," even though county-level sales never exceeded *4.25%* anywhere in the country. Pet. 9.[1] EPA also erected an extraordinary waiver regime to bar a hearing. EPA's waiver rules only heighten the need for review here. But even excluding the evidence that EPA erroneously says was waived, there was more than ample evidence to require a hearing.

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[1] EPA derides the 4.25% figure as "*sales* data." Opp. 14 (emphasis in original). But sales data is a common-sense way of gauging use. And in any event, quibbling at the margins of petitioners' 4.25% figure in no way accounts for EPA's wildly inaccurate *100%* figure.

In the 40 years of the FFDCA, EPA has *never* found a single disagreement with its positions that it believed sufficient to give rise to a material issue of fact requiring a hearing. Not one. And EPA already has seized on the decision below to deny a subsequent hearing request—by an environmental group challenging the safety of a product. *Id.* at 13. Because that decision not only eviscerates a critical statutory hearing right, but does so in a manner that directly conflicts with the decisions of this Court and other circuits, this Court's review is warranted.

I. THE QUESTION PRESENTED IS UNDENIABLY IMPORTANT

EPA cavalierly states that the decision below raises "no issue of broad importance." Opp. 27. Associations representing companies across the country engaged in agricultural crop protection, chemistry, manufacturing, pharmaceuticals and biotechnology, and food and beverages, as well as millions of American farmers and nonprofit public interest organizations dedicated to studying the impact of government on Americans, all disagree. *See* Br. of Amici American Chemistry Council *et al.* (ACC Br.); Br. of Amici CropLife America *et al.* (CropLife Br.); Br. of Amici Pacific Legal Foundation *et al.* (PLF Br.). As they have explained, those organizations are all directly affected by the District of Columbia Circuit's decision in this case. And they all agree that "[t]his case raises fundamentally important issues of administrative law warranting this Court's review." CropLife Br. 2; *see* ACC Br. 4 ("question presented is of exceptional importance"); PLF Br. 2 (case of "vital concern").

These amici recognize that the decision below is by no means "limited to carbofuran or pesticides alone,"

PLF Br. 7, but rather will "likely have a significant negative impact on American industrial concerns." ACC Br. 11. Indeed, amici have explained that "[i]t does not overstate the case to say that the decision below gives the EPA *carte blanche* to determine the fate of literally thousands of products in the market," including prescription drugs, medical devices, agriculture, cosmetics, food products, and other consumer goods. PLF Br. 7; *see* ACC Br. 12. As amici have further explained, Congress has adopted analogous hearing requirements "in several statutes empowering agencies to ban products, and the vast majority of agency decisions are subject to review in the [District of Columbia] Circuit." CropLife Br. 4; *see* ACC Br. 15-17 (discussing "[n]umerous other governmental agencies [that] employ" analogous summary judgment-type procedures). Moreover, amici have explained that statutory hearing rights like the one at issue here "protect[] American industry and consumers from misinformed, ill-conceived regulation of a staggering array of products." ACC Br. 12.

Amici also recognize that the decision directly conflicts with the decisions of this Court and other circuits involving analogous regulatory hearing requirements. CropLife Br. 14-15; PLF Br. 13-14; *see also* ACC Br. 8. EPA unpersuasively attempts to distinguish those cases on the basis of distinctions that it did not draw below. *See* Opp. 24-27; pp. 7-9, *infra*. But the District of Columbia Circuit's *decision* is by no means limited by the *post hoc* distinctions EPA attempts to draw. Instead, the court's ruling is grounded on broadly applicable principles governing what constitutes a "material issue of fact" and what standard of judicial review applies to an agency's

determination that one does not exist. These principles apply directly to numerous other administrative summary judgment-type schemes. Pet. App. 6a-7a. That is why such a broad swath of American industry, farmers, and others are so concerned about the decision below. EPA has no persuasive response.

II. DESPITE EPA'S ATTEMPT TO RECAST IT, THE DECISION BELOW IS SHARPLY OUT OF STEP WITH EXISTING PRECEDENT

EPA offers little defense of the District of Columbia Circuit's remarkable conclusion that a "dispute between experts," Pet. App. 13a, on the outcome-determinative issue of water safety did not entitle petitioners to a hearing under EPA regulations establishing that it "*must* hold a hearing if it determines an objection raises a material issue of fact," *Id.* at 6a (emphasis added). Instead, the agency's main contention is that this Court should simply ignore that far-reaching ruling. That argument is unavailing.

The District of Columbia Circuit held that this case is "accurate[ly]" described as a "dispute between experts." *Id.* at 13a. And that conclusion is unassailable. Petitioners submitted "extensive Comments in response to the proposed revocation," *id.* at 5a, along with 44 expert reports, studies, and analyses on human health/dietary and water risk issues alone. *See* Add. 1a-8a. Petitioners' objections and request for hearing similarly identified with particularity the numerous evidentiary submissions supporting their position and the asserted flaws with EPA's conclusions. *See* Pet. App. 440a-55a. EPA's refusal to recognize "any 'expert' opinion that could have created a legitimate factual dispute in this case," Opp. 14 (citation omitted); *see id.* at 15, simply

underscores that EPA categorically rejects *any* contrary expert opinion.

The District of Columbia Circuit's holding that this prototypical expert dispute over water safety did not require a hearing is part and parcel of the judgment under review. Without any "in any event" or other qualifying language, the court expressly acknowledged the "dispute between experts" over groundwater safety; held that it was "fatal" to petitioners' case; and immediately thereafter held that "petitioners have failed to show a hearing was warranted on either of the first two issues of fact they raised," explaining that "we will not overturn an agency's finding there is no material issue of fact based upon '[m]ere differences in the weight or credence given to particular studies.'" Pet. App. 13a (citation omitted). At a bare minimum, that holding warrants further review.

If "mere differences" in expert testimony or reports concerning "outcome-determinative" facts like safety are not sufficient to warrant a hearing, nothing is. EPA has made clear that *non-expert* testimony and objections shall be treated as "mere allegations and general denials and contentions, which EPA regulations expressly provide to be insufficient to justify a hearing." 74 Fed. Reg. 59,608, 59,622 (Nov. 18, 2009); *id.* at 59,622-23 (citing 40 C.F.R. § 178.32). And the decision below gives the agency *carte blanche* to decide what *expert* testimony—if any in the agency's view—is sufficient to warrant a hearing. So in the wake of the District of Columbia Circuit's decision in this case, a party like petitioners here opposing EPA's decision to ban a product used safely for decades can *never* obtain a hearing except by EPA grace—

something EPA has not seen fit to exercise in the four decades it has administered the hearing right at issue.

That result is directly at odds with the precedents of this Court and other courts. Pet. 20-26. As this Court made clear in *Weinberger v. Hynson, Wescott & Dunning, Inc.*, summary judgment is appropriate *only* where "the applicant has not tendered *any* evidence which *on its face* meets the statutory standards as particularized by the regulations." 412 U.S. 609, 620 (1973). There can be no serious dispute that petitioners' evidence satisfies *that* standard. Pet. 20-21. And in *Weinberger* this Court upheld the Fourth Circuit's conclusion that a hearing was required to resolve a "battle of the experts" under a directly analogous hearing provision. *Id.* at 23-24.

EPA never seriously attempts to account for the direct conflict with *Weinberger*. First, EPA weakly suggests that this Court "did not explain its rationale" in finding that a hearing was required in *Weinberger*. Opp. 25. But as discussed, the decision below directly conflicts with several different facets of this Court's explicit holdings in *Weinberger*, not to mention the Fourth Circuit decision *upheld* in *Weinberger*. Pet. 20-24. Next, EPA says that *Weinberger* involved different "statutory and regulatory provisions." Opp. 25. But the District of Columbia Circuit's decision in this case did not rely in any way on the purported statutory distinctions that EPA now attempts to draw. More to the point, EPA itself has explicitly acknowledged that its "hearing request requirements are based *heavily* on FDA [hearing] regulations," Pet. App. 82a (emphasis added), which FDA has made clear "accurately reflect the legal standards enunciated by" *Weinberger*, 40 Fed. Reg. 22,950, 22,968 (May 27, 1975).

In any event, EPA's statutory argument (Opp. 22-23)—based on Section 408(g)'s use of "determine[]" and "necessary"—fails on two different levels. First, the language on which EPA now relies was added in 1996 and thus *post-dates* EPA's own hearing regulation. *Compare* Food Quality Protection Act of 1996, Pub. L. No. 104-170, § 405, 110 Stat. 1489, 1525 *with* 55 Fed. Reg. 50,282, 50,292 (Dec. 5, 1990). EPA's regulations explicitly provide that "[a] request for an evidentiary hearing *will be granted*" if "'[t]here is a genuine and substantial issue of fact for resolution.'" Pet. App. 3a (emphasis added) (quoting 40 C.F.R. § 178.32(b)). The 1996 amendments by no means intended to alter that rule. *See* H.R. Rep. No. 104-669, pt. 2, at 49 (1996) (Congress "expects EPA ... to grant hearings to responsible parties *on all sides*") (emphasis added). And second, EPA's argument simply proves too much and only further underscores that EPA seeks essentially unreviewable discretion to make hearing determinations. *Cf. Massachusetts v. EPA*, 549 U.S. 497, 533 (2007) (provision of "judgment" to EPA is not a limitless grant of authority, but rather "a direction to exercise discretion within defined statutory limits").

The District of Columbia Circuit's holding concerning when a material issue of fact exists also directly conflicts with the decisions of the Fourth and Ninth Circuits recognizing that administrative hearings are required under analogous summary judgment-type procedures when a party demonstrates a "genuine and substantial issue of fact." *Hynson, Westcott & Dunning, Inc. v. Richardson*, 461 F.2d 215, 219 (4th Cir. 1972); *see also Pactra Indus., Inc. v. CPSC*, 555 F.2d 677, 684 (9th Cir. 1977) (Kennedy, J.). Indeed, in *Pactra*, the court held that a hearing may

not be denied "merely because *the agency* has concluded that the scientific evidence is adequate to support its order." 555 F.2d at 684 (emphasis added). The basic conflict concerns *when* an expert dispute creates a material issue of fact. The distinctions that EPA now attempts to draw among the underlying provisions are non-responsive because EPA has already "agree[d]" that it "*must* hold a hearing" under the FFDCA when such a disputed issue of material fact exists. Pet. App. 6a (emphasis added).

III. EPA'S NOVEL WAIVER REGIME ONLY HEIGHTENS THE NEED FOR REVIEW

Rather than addressing the District of Columbia Circuit's decision on its own terms or genuinely accounting for the multiple conflicts presented, EPA suggests that this case is "a poor vehicle" for addressing the important question presented because of what EPA calls petitioners' "serial waivers." Opp. 14. But EPA has it backwards. EPA's "Catch 22" waiver rules—which were upheld by the decision below—only further trample on the FFDCA's hearing requirement and thus increase the need for review.

Although the government is invariably fond of invoking waiver principles, the waiver rules at issue here are by no means custom fare. As explained, EPA's waiver rules not only conflict with the text of the relevant statutory and regulatory provisions, they effectively ensure that virtually *any* argument may be rejected on the ground that they were raised *too early* or *too late*. Pet. 27-29. For example, because EPA's rules treat as waived "'any issue not originally raised in comments,'" Opp. 17 (citation omitted), petitioners submitted substantial comments and expert evidence refuting EPA's factual determinations. At the

objections and hearing request stages, however, EPA refused to consider those comments and supporting evidence on the ground that they were "recycled" from the earlier phase. 74 Fed. Reg. at 59,609.

The court of appeals nevertheless broadly affirmed this "Tails-I-Win, Heads-You-Lose" waiver regime. Under the court's decision, when a petitioners' submissions fail to convince the agency to alter its own proposed regulation or analysis in its final regulation, a petitioner is powerless to obtain a hearing, even when its comments or objections raised a material issue of fact. And that is true even when EPA's analysis on outcome-determinative issues *changes* from the the *Proposed Rule* to the *Final Rule*. Pet. 28-29. The upshot is that EPA's waiver rules essentially leaves the agency free to ignore whatever submissions it deems inconvenient. And under the decision below, the courts must disregard evidence EPA deems waived in determining whether a hearing is required, even when it is undisputed that the evidence was before EPA.[2]

Administrative exhaustion requirements typically ensure the presentation of an issue to allow for full agency consideration and to "'produce a useful record for subsequent judicial consideration.'" *Woodford v. Ngo*, 548 U.S. 81, 89 (2006) (citation omitted). In contrast, the EPA's waiver regime—upheld by the decision below—enables the agency to *avoid* the development of a record and to *preclude* judicial review

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[2] EPA's rehearing analogy (Opp. 18) is fundamentally flawed. It is not unusual for a petition for rehearing to renew arguments made in the principal briefs. Moreover, making an argument on rehearing by no means prevents a party from making it in the next stage of review. In EPA's Orwellian waiver parlance, however, such arguments would be "recycled," and thus waived.

altogether. Moreover, EPA's waiver rules do not encourage the presentation of the right issues to the right tribunal at the right time; they create a no-win gauntlet with no basis in the statute or regulations, which a petitioner's genuine hearing request cannot survive unless EPA so chooses. Not surprisingly, the District of Columbia Circuit's decision embracing that extraordinary regime conflicts with the decisions of this Court and other circuits. Pet. 29-31.

This case aptly illustrates how EPA's waiver rules operate systematically to destroy genuine hearing requests. Petitioners conscientiously presented expert report after expert report at every stage of the proceedings to establish what ought to follow as a matter of common sense in light of the lack of evidence that carbofuran posed any harm during the 40 years it was used at much higher levels: there is, at the very least, a material issue of disputed fact concerning whether carbofuran is safe, especially at the relatively low levels at issue here. Yet EPA managed to shred that hearing request through the application of its whip-saw waiver rules, and the District of Columbia Circuit's decision broadly affirms that result. That far-reaching decision warrants this Court's review.

CONCLUSION

For the foregoing reasons, and those in the petition, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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ADDENDUM

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Compilation of Expert Materials Submitted to EPA in Administrative Proceedings and List of Experts That Presented Materials

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EXPERT MATERIALS RELATING TO GROUND WATER AND SURFACE WATER EXPOSURES

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19. * Barraj, L. and Polakoff, B., *Carbofuran Dietary Risk Assessment* (June 30, 2009).

20. * Hoogeweg, G. and Williams, W.M., *Groundwater pH in selected states.* Memo to Dylan Fuge, Latham & Watkins (June 30, 2009).

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* An asterisk denotes material that was submitted to EPA during the administrative proceedings below but which EPA has claimed was waived under the waiver rules at issue. As explained in the certiorari petition and this reply brief, those rules should not be given effect. But in any event, as these tables illustrate, the vast majority of expert materials presented by petitioners are not subject to waiver claims at all

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